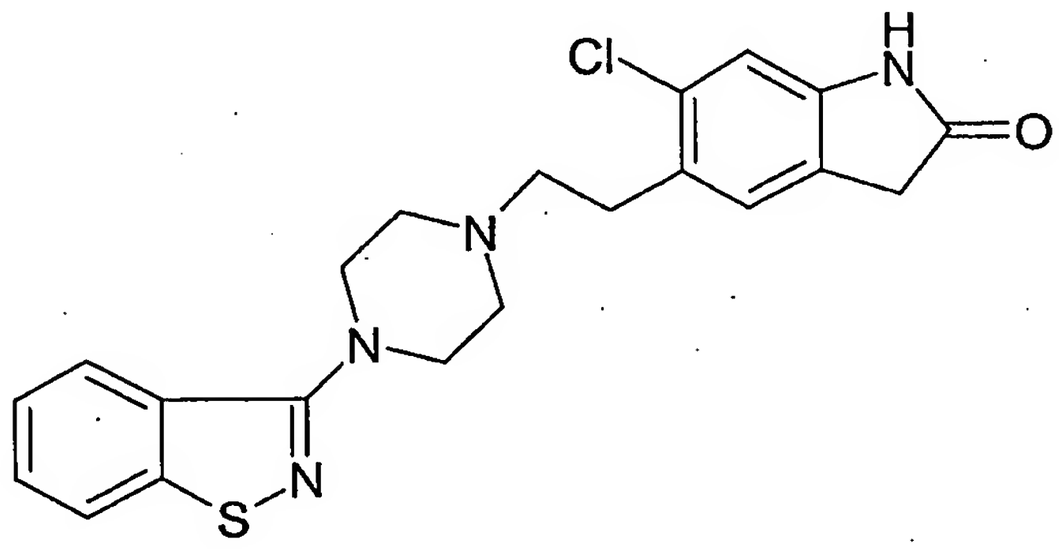
WE CLAIM:

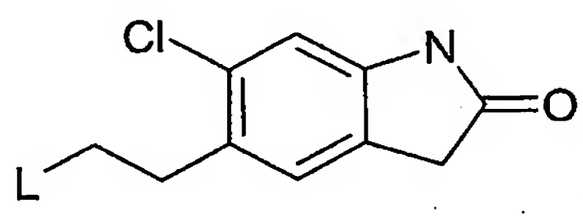
1. A process for the preparation of ziprasidone base of Formula I, or a salt thereof,



FORMULA I

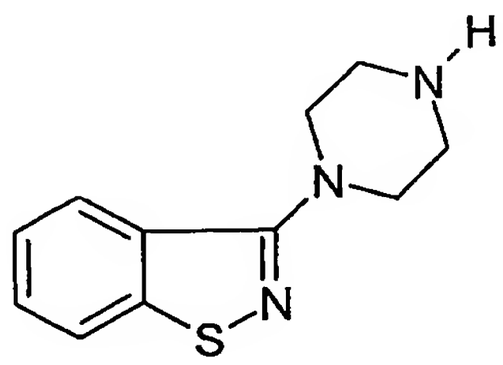
the process comprising:

reacting a compound of Formula II,



FORMULA II

wherein L is a leaving group, with 1-(1,2-benzisothiazol-3-yl)piperazine of Formula III,



FORMULA III

in water in absence of a base to form a mixture;

heating the resultant mixture to from about 50°C to reflux temperature; and

isolating the ziprasidone base of Formula I, or a salt thereof.

2. The process of claim 1, wherein the leaving group L is selected from the group consisting of chloro, bromo, iodo, mesyloxy, tosyloxy or acetyloxy.

3. The process of claim 1, further comprising heating the mixture in the presence of an organic solvent.

4. The process of claim 3, wherein the organic solvent comprises one or more of alcohols, ketones, polar aprotic solvents, esters, or mixtures thereof.

5. A process for the preparation of substantially pure ziprasidone base, the process comprising:

obtaining a suspension of ziprasidone in one or more solvents;

heating the suspension to get a clear solution; and

recovering the substantially pure ziprasidone by the removal of the solvent.

6. The process of claim 5, wherein the solvent comprises one or more of lower alkanol, ether, ketone, chlorinated hydrocarbon, polar aprotic solvent, water, or mixtures thereof.

7. The process of claim 6, wherein the lower alkanol comprises one or more of methanol, ethanol, n-propanol, and isopropanol.

8. The process of claim 6, wherein the ether comprises one or both of tetrahydrofuran, and 1,4-dioxane.

9. The process of claim 6, wherein the ketone comprises one or more of acetone, ethyl methyl ketone, methyl isobutyl ketone, and diisobutyl ketone.

10. The process of claim 6, wherein the chlorinated hydrocarbon comprises one or more of chloroform, dichloromethane, and 1,2-dichloroethane.

11. The process of claim 6, wherein the polar aprotic solvent comprises one or more of N,N-dimethylformamide, N,N-dimethylacetamide, dimethylsulfoxide, acetonitrile, and N-methylpyrrolidone.

12. The process of claim 5, wherein the suspension is heated from about 40°C to reflux temperature.

13. The process of claim 5, wherein removing the solvent comprises one or more of distillation, distillation under vacuum, evaporation, filtration, filtration under vacuum, decantation, and centrifugation.

14. The process of claim 13 further comprising adding additional solvent before removing the solvent.

15. The process of claim 5, wherein the substantially pure ziprasidone, or a salt thereof is recovered from the solution by distillation.

16. The process of claim 15, wherein the distillation is carried out under vacuum.

17. The process of claim 5, wherein the substantially pure ziprasidone is recovered from the solution by filtration.

18. The process of claim 5, further comprising additional drying of the product obtained.

19. The process of claim 5, further comprising cooling before removing the solvent.

20. Ziprasidone base having a purity of more than 99.8% wherein total impurities are less than 0.2% when determined by HPLC.

21. Ziprasidone base having a purity of more than 99.9% wherein total impurities are less than 0.1% when determined by HPLC.

22. A process for the preparation of substantially pure ziprasidone hydrochloride, the process comprising:

obtaining a suspension of ziprasidone in one or more solvents;

contacting the suspension with hydrogen chloride to form a solid; and

isolating the ziprasidone hydrochloride in substantially free form.

23. The process of claim 22, wherein the solvent comprises one or more of lower alkanols, chlorinated hydrocarbons, aromatic hydrocarbons, polar aprotic solvents, ethers, ketones, or mixtures thereof.

24. The process of claim 22, wherein the solid is washed with water, polar aprotic solvent, lower alkanol, ether, or mixtures thereof before isolation.

25. The process of claim 24, wherein the solid is washed till the washings are free of any acidity.

26. The process of claim 22, further comprising additional drying of the product obtained.

27. The process of claim 22, further comprising forming the product obtained into a finished dosage form.

28. Ziprasidone hydrochloride having a purity of more than 99.8% with total impurities less than 0.2% when determined by HPLC.

29. Ziprasidone hydrochloride having a purity of more than 99.9% with total impurities less than 0.1% when determined by HPLC.

30. A pharmaceutical composition comprising a therapeutically effective amount of substantially pure ziprasidone hydrochloride, and one or more pharmaceutically acceptable carriers, excipients or diluents.

31. A method of treating schizophrenia in a warm-blooded animal, the method comprising providing a dosage form to the warm-blooded animal that includes substantially pure ziprasidone hydrochloride.